UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456**
	)	**Master File No. 01-12257-PBS**
	)	**Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: **State of California, *ex rel.* Ven-A-Care v. Abbott Laboratories, *et al.*** **03-CV-11226-PBS**	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS THE FIRST AMENDED COMPLAINT IN INTERVENTION

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I.
INTRODUCTION

A. BACKGROUND

In this action, Plaintiffs California and Ven-A-Care of the Florida Keys are suing pharmaceutical manufacturers, alleging each has defrauded California's Medicaid program, known as Medi-Cal. Plaintiffs allege that Defendants deliberately reported false and inflated pricing information to national pharmaceutical price reporting compendia, including Average Wholesale Price (AWP) and Direct Price (DP). Medi-Cal relied upon the reported prices in setting reimbursement rates for providers who prescribe and dispense Defendants' pharmaceutical products to California's young, poor, elderly and disabled Medi-Cal population. Defendants knew Medi-Cal used the prices reported by them to determine reimbursement. Defendants are not required by any law to participate in Medi-Cal. Rather, they take affirmative steps to render their drug products eligible for reimbursement under Medi-Cal. One necessary step is to report pricing information to the national companies. *See* Plaintiffs' First Amended Complaint in Intervention (FAC) ¶¶ 27-36.

Defendants benefit greatly when the drugs they manufacture are paid for by Medi-Cal. The Medi-Cal program is the main source of health insurance for about 6.5 million Californians, draws nearly $19 billion in federal funds into the state's health care system, and accounted for 14% of California's General Fund spending in fiscal year 2005-2006.[1] Medi-Cal is the largest Medicaid program in terms of people served, the second largest in terms of dollars spent ($34.4 billion), and the primary (if not exclusive) source of health coverage for one in six Californians

1. California Healthcare Foundation, *Medi-Cal Facts and Figures: A Look at California's Medicaid Program* 1 (January 2006), in pdf format at http://www.chcf.org/topics/medi-cal/index.cfm?itemID=21659.

under 65, one in four of the state's children, and the majority of Californians living with AIDS.[2] In 2002 alone, Medi-Cal spent more than $3.4 billion for drugs on behalf of over 2.65 million Medi-Cal beneficiaries.

Defendants have engaged in a complex, pervasive and sophisticated scheme to misrepresent prices generally and currently available to Medi-Cal providers, and to make it extraordinarily difficult to discover the true acquisition costs. A central purpose of this scheme is to create and foster a source of enhanced profit for Medi-Cal providers, intended to induce them to prescribe or buy Defendants' drugs, all at the expense of the Medi-Cal program. Many of the Defendants' arguments in their Motion to Dismiss appear to be based upon the flawed assumption that drug manufacturers, when dealing with government healthcare programs, are free to conduct themselves in all respects in the same manner they would when dealing with commercial parties in arms-length transactions. The requirements of the California False Claims Act ("CFCA")(CAL. GOV'T CODE §§ 12650-12656) and Medi-Cal anti-kickback Statute ("AKS") (CAL. WELF. & INST. CODE §14107.2), like their federal counterparts, impose additional requirements upon the Defendant Manufacturers. It is well-settled law that the Defendants had a duty to familiarize themselves with the legal requirements of the Medicaid Programs in which their drug products play a prominent role in addressing the health needs of the impoverished and elderly. *See.,e.g.*, *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984); *North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995). Each of the Defendants deliberately chose, but certainly were not required, to have Medi-Cal reimburse for their drugs, and each knew that their drugs would not be reimbursed unless

2. California Healthcare Foundation, *Medi-Cal Facts and Figures: A Look at California's Medicaid Program*, supra, at 3, 5.

the Defendants reported or caused their prices to be reported to the compendia. Defendants' actions have violated the CFCA and AKS. Plaintiffs seek appropriate damages for California and its Medi-Cal program under the CFCA.

B. STANDARD OF REVIEW

"[A] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the [non-moving party] can prove no set of facts in support of his claims that would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957) (footnote omitted). In short, "[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). When addressing a motion to dismiss, it is incumbent upon the Court to accept " 'the allegations in the complaint as true and mak[e] all reasonable inferences in favor of plaintiff'". *Doran v. Mass. Tpk. Auth.*, 348 F.3d 315, 318 (1st Cir. 2003), quoting *Rockwell v. Cape Cod Hosp.*, 26 F.3d 254, 255 (1st Cir. 1994). Ordinarily, a court may not consider any documents outside the complaint, or not expressly incorporated into the complaint, unless the motion is converted into one for summary judgment. *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33-34 (1st Cir. 2001).

Federal Rule of Civil Procedure Rule 9(b) states, "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." "Rule 9(b) requires that a plaintiff's averments of fraud specify the time, place, and content of the alleged false or fraudulent misrepresentations." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004). In contrast, however, "[m]alice, intent, knowledge and other conditions of minds or a person may be averred generally." FED. R. CIV. P. 9(b).

C. PLAINTIFFS' ALLEGATIONS IN SUMMARY

While Defendants repeatedly refer to the exhibits improperly attached to Defendants' Joint Memorandum ("DJM"), they steer assiduously clear of Exhibits A-H, J, K, and M-O attached to the FAC, ignoring the 534 pages of substantive reimbursement and market pricing detail provided in support of Plaintiffs' FAC. In fact, not one Defendant challenges the adequacy of the reimbursement and actual market price information depicted in the sealed exhibit served on that Defendant, or the spread represented in the difference between those two sets of numbers as portrayed in the pertinent sealed exhibits' 534 pages. Defendants' silence regarding Plaintiffs' pricing exhibits speaks volumes, as it is the FAC's allegations and supporting exhibits which must determine the outcome of Defendants' motion to dismiss.

1. The Actions of Defendants in Reporting False Prices to the Compendia Eviscerate the Objective of Linking Medi-Cal Reimbursement to Estimated Acquisition Prices.

Defendant drug manufacturers sell their products through various intermediaries to Medi-Cal providers, who then dispense drugs to Medi-Cal patients and bill California's Department of Health Services (DHS) for reimbursement. DHS, which administers Medi-Cal, reimburses providers for each pharmacy claim based on an amount termed the Cost of the Drug Product (CDP), which is defined under California law as the lowest of the drug's Estimated Acquisition Cost (EAC), Federal Allowable Cost (FAC [the same as the FUL]), or Maximum Allowable Ingredient Cost (MAIC) for the Standard Package size, or the amount billed by the provider. EAC is further defined as either AWP minus a determined percentage, or DP. FAC ¶¶ 1-22, 26-31. Providers submit reimbursement claims through electronic filing or on hard copy forms. Between 1994 and 2004 Medi-Cal handled over 716 million pharmacy claims, or on average

1.37 million per week, or 274,000 per weekday. AWP, DP and FUL, prices used by Medi-Cal to set reimbursement, are published in compendia such as First Databank (FDB), which is the primary reference compendia used by Medi-Cal. FDB receives its prices from the manufacturers and distributes such pricing on a national level. Defendants control the AWP and DP prices that are reported to FDB. Plaintiffs' sealed exhibits document the disparities between AWP and generally and currently available prices known to Plaintiffs, even at this pre-discovery stage of the case. The gross disparities between the AWP and other pricing information controlled by Defendants and reported to the compendia, compared to the acquisition costs enjoyed by providers in purchasing Defendants' drugs, established a "spread" between provider's market acquisition costs and reimbursement levels. FAC ¶¶ 31-42; Exhibits A-H, J, K, and M-O.

2. Defendants Have Intentionally Engaged in a Scheme Which Caused California to Pay Hundreds of Millions of Dollars in Excess of the Generally and Currently Available Prices for Prescription Drugs.

Defendants compete with each other by marketing the spread. The actual prices for Defendants' drugs as sold directly through wholesalers are much lower than reported AWP, DP, or other prices reported by Defendants. Defendants offer providers additional favorable contract terms, further driving down the drugs' costs. FAC ¶¶ 43-46. Defendants have inflated their AWPs to levels far in excess of any real wholesale price of their drugs. FAC ¶¶ 50-176. The FAC alleges that Defendants market the spread to providers in order to sell more of their drug product, thereby increasing their market share and profits. FAC ¶¶ 53, 57, 61, 66, 70, 74, 82, 101, 111, 120, 136, 174; Exhs. A-H, J, K, M-O.

II.
ARGUMENT

A. DEFENDANTS' ARGUMENTS BASED ON OSTENSIBLE GOVERNMENT KNOWLEDGE MUST BE REJECTED PROCEDURALLY, FACTUALLY AND LEGALLY

Defendants' "factual" section regarding government knowledge (DJM 8-11) and their legal argument premised on these ostensible facts (DJM 22-24) must fail because (1) judicial notice is improper, (2) the particular "knowledge" selectively highlighted by Defendants is but one part of a complex puzzle, and (3) as a matter of law, Defendants' "facts" do not warrant dismissal. Plaintiffs separately move to exclude from consideration Defendants' overly broad and inaccurate conclusions drawn from their exhibits which purport to prove California's knowledge and acceptance of Defendants' misconduct. As explained in detail in Plaintiffs' Objections to Judicial Notice[3] (filed contemporaneously with the instant Opposition to Defendants' Motion to Dismiss), taking judicial notice of their exhibits for the conclusions Defendants advance is improper under Federal Rule of Evidence Rule 201(b). This is because: (1) the exhibits do not support the purported conclusions, (2) judicial notice is generally inappropriate regarding the contents of reports as compared to their existence, and (3) the conclusions are not "facts not subject to reasonable dispute" or "capable of ready and accurate determination." FED. R. EVID. 201(b). Once Defendants' improper attempt at judicial notice is rejected, their entire argument regarding government knowledge fails for lack of factual support.[4]

3. Captioned "Plaintiffs' Objections Pursuant to Rule 201(e) of The Federal Rules of Evidence to Judicial Notice of Facts And Conclusions Set Forth in Defendants' Motion to Dismiss."

4. Similarly, Defendants' frequent references to federal Medicaid rebates or state supplemental rebates are of no moment. Plaintiffs' FAC is not premised on rebate issues. Whether by request for judicial notice or other means, this Court should not permit Defendants to introduce evidence about rebates at this stage because any discussion about rebates is utterly foreign to the allegations set forth in the FAC. Significantly, Defendants offer no actual legal argument in support of dismissal in their cursory representations concerning rebates.

Additionally, Defendants' arguments are incorrect legally. After years of reporting falsely inflated prices to the pricing compendia, Defendants now have the audacity to ask that this Court absolve them from any responsibility for their deliberately fraudulent acts by contending that Medi-Cal knew, all along, that it was being deceived. Defendants argue that such "government knowledge" defeats any allegations of falsity and precludes a finding of scienter. *See* DJM at 22 (government's knowledge precludes finding of falsity) and 24 (government's knowledge "also serves to negate the intent necessary to support a false claims act claim"). However, government knowledge of the falsity of a claim or statement, standing alone, does not defeat a claim under the False Claims Act ("FCA").[5] *See Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534-35 (10th Cir. 2000) (holding that 1986 amendments to False Claims Act make clear that government knowledge of a defendant's wrongdoing is not an automatic defense); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("[t]hat the relevant government officials know of the falsity is not in itself a defense"). This follows because the focus of the California False Claims Act ("CFCA") is on the *defendant's* conduct and knowledge. CAL. GOV'T CODE § 12651(a). The federal law, of course, is the same. *See* 31 U.S.C. § 3729(a),(b).

Government knowledge can sometimes be a first step towards judgment as a matter of law for defendants, but only in very limited circumstances. The government must be fully apprised of the details of the alleged falsity and must agree to the course of conduct. Indeed, contrary to Defendants' assertions regarding government knowledge and falsity, most cases

5. California courts have determined that precedent under the federal False Claims Act is relevant to issues under California's very similar statute. *State v. Altus Finance*, 36 Cal. 4th 1284, 1299 (2005) (appropriate to look at precedent construing the equivalent federal act).

make clear that the extent of the government's awareness of ostensibly false claims is only relevant on a motion to dismiss if that awareness actually negates an allegation that defendants could have acted with scienter. *See, e.g., United States ex rel. Butler v. Hughes Helicopters*, 71 F.3d 321, 327 (9th Cir. 1995) ("if the district court correctly found that the only reasonable conclusion a jury could draw from the evidence was that [the defendant] and [the governmental agency] had so completely cooperated and shared all information during the testing that [the defendant] did not 'knowingly' submit false claims, then we must affirm the directed verdict"); *Hagood*, 929 F.2d at 1421 (same); *United States v. White*, 765 F.2d 1469, 1482 (11th Cir. 1985) (only active government misleading or approval of the conduct at issue can negate defendants' fraudulent intent).

Tellingly, Defendants' cited cases regarding government knowledge fit squarely in the mold that affirmative government conduct is necessary to defeat a False Claims Act claim. For example, in *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542 (7th Cir. 1999), the court explained the link between the government's involvement and defendants' possible fraudulent intent as follows: "If the government knows *and approves* of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." *Id.* at 545 (emphasis added). In *American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854 (2001), the allegations concerned a bid process that the government agency ultimately rejected in favor of a sole-source contract with one bidder. On the *state's* motion to dismiss, the court stated: "[t]he critical factor present in both *Durcholz* . . .[and a related case], as well as the instant matter, is that the claim for payment was somehow defective, but the defect [sole source bidding] was known to *and initiated by the*

government." *Id.* at 865 (emphasis added). Similarly, in *Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795 (D. Utah 1988), the court relied on the excessively detailed knowledge and explicit acquiescence of NASA regarding the alleged defects. *Id.* at 809-10 (close interplay between defendant and NASA regarding design, testing and performance of seals and joints at issue).

Nothing in the FAC or even in the Defendants' inappropriately tendered "government reports" remotely suggests that Medi-Cal or DHS instructed Defendants not to report truthful pricing. There is not a whiff of evidence that (1) Defendants communicated with the government about their interpretation of AWP or their supposed inability to understand what was expected of them, (2) that Defendants informed the government of their marketing schemes centered on the creation of a spread or inducement to providers to utilize their drugs, all at the financial expense of the Medi-Cal program, or (3) that the government understood and endorsed a system whereby drug manufacturers randomly, secretly and self-servingly set Medi-Cal reimbursements and the amount of profit to providers, with total disregard for the regulatory mandate to link drug product reimbursement to estimated acquisition costs or prices generally and currently available to providers. To the contrary, the allegations are manifest that Defendants chose to submit false information to FDB, while at the same time they concealed the truth. Any attempt by Defendants to defeat the falsity or especially the intent element of the CFCA claims against them is unsupported and is premature on a motion to dismiss. *See, e.g., United States ex rel. Butler v. Hughes Helicopters*, supra, 71 F.3d at 327 (possible that at or after trial the extent and nature of the government's knowledge could show that Defendants did not have intent required); *In re Pharm. Indus. Average Wholesale Pricing Litig.*, 321 F. Supp. 2d 187, 206 (D. Mass. 2004) (declining to reach government knowledge arguments on motion to dismiss). Defendants'

procedurally inappropriate, factually unsupported and legally insufficient invocations of a government knowledge defense must be disregarded in their entirety.

B. ALL FIVE CAUSES OF ACTION IN THE FIRST AMENDED COMPLAINT STATE VIABLE CLAIMS AND SHOULD NOT BE DISMISSED UNDER FED. R. CIV. P. 12(b)(6)

1. All Five Causes Of Action Allege The Submission Of A False Claim

Defendants are correct that Plaintiffs' claims are based upon the CFCA, CAL. GOV'T CODE §§ 12650-12656, and that under either §§ 12651(a)(1) or (a)(2), the submission of a false claim must be alleged. Defendants, however, read the claims submission requirements too restrictively and ignore the facts that are alleged throughout the FAC. By focusing on the providers' claims submissions in isolation, Defendants attempt to obfuscate the material conduct which forms the basis of the FAC. In this case, as in *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 320 (D. Mass. 2005) and *In re: Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148 (D. Mass. 2003), Plaintiffs allege that Defendants report materially inflated AWPs to third-party publishers, which, in turn, cause California to pay excessive amounts to pharmacy providers. Defendants' argument is a classic "red herring."

The Supreme Court has consistently held that the federal FCA, which is very similar to the CFCA, is to be construed broadly rather than restrictively. In *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968), the Court stated that the FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *See also, United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 186 (D. Mass. 2001) (a person need not directly submit claims to the government to be liable). The CFCA, as interpreted by California courts, is no less sweeping:

> [Defendants] argue that they cannot be liable in any event, for [defendants] had no knowledge that the City would be the end user of products it supplied to distributors. This signifies nothing. [Defendant] certainly intended to attract every potential customer such as the City that it could attract . . . That is enough to make [Defendant] liable for the fruits of its endeavors. It would not serve the purposes of the California False Claims Act to adopt any other rule. Leaving manufacturers free to cause the submission of false claims to governmental entities simply because they had no certain knowledge that a particular entity would become a consumer of its products would not serve to prevent fraud upon the government.

City of Pomona v. Superior Court, 89 Cal. App. 4th 793, 805 (2001) (citations omitted). Here, there is no confusion over the fact that Defendants' fraudulent conduct led to the submission of false claims to California's Medi-Cal program. Nor can Defendants plausibly complain that the FAC leaves them in doubt as to *whether* any false claims were submitted. Plaintiffs allege with specificity that each Defendant knowingly caused the submission of false claims for reimbursement for the drug products they manufactured. FAC ¶¶ 50-175. Moreover, the FAC explicitly alleges the submission of false claims, in paragraph 42.

Even assuming the absence of the express allegations, above, Defendants ignore that throughout the FAC, Plaintiffs allege that Defendants reported excessively high and false prices (FAC ¶¶ 1, 36, 42, 43, 44, 49, 50), with knowledge that the reported prices would be used by Medi-Cal for reimbursement to providers based upon claims which were submitted. (FAC, ¶¶ 37, 42, 49, 178). Under the standard which must underpin a court's analysis on a motion to dismiss, it is incumbent upon the Court to accept "'the allegations in the [FAC] as true and make all reasonable inferences in favor of [Plaintiffs].'" *Doran*, 348 F.3d at 318 (citation omitted). The only inference that can be drawn from the facts alleged in the FAC is that *false claims were*

submitted and that Defendants caused the submissions to occur.[6]

Defendants' reliance upon *United States v. Rivera,* 55 F.3d 703 (1st Cir. 1995) to argue that there must be a false claim submission to the government for liability to attach under the FCA misses the mark. First, as noted above, Plaintiffs have alleged the submission of false claims throughout the FAC. Second, *Rivera* does not hold that liability under the FCA is strictly limited to those instances where a defendant submits false claims directly to the government. To the contrary, *Rivera* recognizes that liability under the FCA exists if a defendant knowingly assists "in causing the government to pay claims which are grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Rivera,* 55 F.3d at 707, *quoting United States ex rel. Marcus v. Hess,* 317 U.S. 537, 544-45 (1943). While *Rivera* states that the "paradigmatic example of a false claim under the FCA . . . is a false invoice or bill for goods or services," the First Circuit also recognized that "[t]he term . . . applies more generally to other demands for government funds." *Rivera,* 55 F.3d at 709.

Finally, Defendants' arguments that the published AWPs reported by them to the pricing compendia are not part of the claim form, and that the claims were submitted in accordance with instructions, is irrelevant to the fraudulent scheme alleged in this case. Unlike *People v. Duz-Mor Diagnostic Laboratory, Inc.,* 68 Cal. App. 4th 654 (1998), this case is not about a defendant's direct submission of a false claim, but rather the allegations are that Defendants made false statements in support of claims, and caused the submissions of false claims. FAC ¶¶ 36, 38, 42.

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6. Indeed, this Court recognized that when a "suggested inference" "rise[s] to what experience indicates is an acceptable level of probability, ... 'conclusions' become 'facts' for pleading purposes." *Krantz v. Fidelity Mgmt. & Research Co.,* 98 F. Supp. 2d 150, 153 (D. Mass. 2000), quoting *Cooperman v. Individual, Inc.*, 171 F.3d 43, 47-48 (1st Cir. 1999).

2. Plaintiffs Sufficiently Allege That Defendants Caused False Claims To Be Presented.

Defendants argue that the FAC fails to allege that Defendants had any involvement whatsoever in the submission of claims to Medi-Cal. DJM 25. But Plaintiffs allege that Defendants provided false or misleading price information to the compendia, knowing that those prices would be published to the Medi-Cal program and used to set Medi-Cal reimbursements to providers for Defendants' drugs. FAC ¶¶ 1, 36, 42, 43, 44, 49, 50. These allegations are sufficient to show that an intended consequence of Defendants' reporting of price information to the compendia was that Medi-Cal would pay excessive amounts to providers on pharmacy claims. As the California Court of Appeal has underscored, under both state and federal law "*the claim itself need not be false but only need be underpinned by fraud*. . . the language of the [federal] False Claims Act statute does not anywhere state that False Claims Act liability depends upon a defendant's status as a recipient or beneficiary of the fraudulently induced contract." *Pomona*, 89 Cal. App. 4th at 802 (emphasis added).

Defendants' ties to the submission of false claims in this case are even stronger than plaintiff's allegations in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001) (*Parke-Davis I)* and *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, *6 (D. Mass. 2003) (*Parke-Davis II).* Here, no intervening force exists such as the independent actions of pharmacists and physicians. Instead, Plaintiffs allege that Defendants acted knowingly and intentionally to create a spread.

Defendants place heavy reliance upon one case, *United States ex rel. Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011 (D. Minn. 2001). However, this Court has distinguished *Kinney* in a case where evidence presented in a summary judgment motion showed that

defendant's actions were "not irrelevant, but, rather, played a key role in setting in motion a chain of events that led to false claims." *Parke-Davis II*, 2003 WL 22048255 at *6[7]. As this Court stated, the FCA does not provide a special definition for causation:

> [t]he first question is whether there was in fact some causal relationship between the conduct and the outcome. The *Restatement* expresses this test as whether the defendant's conduct was a 'substantial factor in producing the harm.' *Id.* The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test. (Citations omitted).

Id. at *4. A fundamental tenet from *Parke-Davis II* is that a determination of cause is a fact-based, evidentiary inquiry that is not proper for adjudication in a 12(b)(6) motion. 2003 WL 22048255 at *2. This alone is sufficient to deny the motion outright.

Other precedent from this Court further compels denial of Defendants' motion to dismiss. In an earlier decision in *Parke-Davis*, this Court rejected an argument that independent actions of physicians and pharmacists with regard to the writing and filling of off-label prescriptions broke the chain of causation. *Parke-Davis I*, 147 F. Supp. 2d at 52-53. This Court held:

> [W]hen all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

Id. Here, Plaintiffs allege that Defendants provided false or misleading price information to the compendia with knowledge that the information would be reported to the State and utilized by Medi-Cal for drug reimbursement. FAC ¶¶ 1, 36, 42, 43, 44, 49, 50. These allegations are sufficient to show that an intended consequence of Defendants' reporting of price information

7. In *Kinney*, "[a] critical factor was that the ambulance service's computerized accounting system *automatically* coded ambulance runs as 'medically necessary,' and that the physicians' determinations were irrelevant." *Parke Davis II*, 2003 WL 22048255 at * 6.

was that Medi-Cal would pay excessive amounts to providers on pharmacy claims. All reasonable inferences drawn in favor of the Plaintiffs should persuade this Court that sufficient allegations of cause have been alleged and that the motion to dismiss should be denied.

3. Plaintiffs Have Adequately Alleged That Defendants' AWPs And DPs Are False.

Defendants argue that their AWPs and DPs are not false because California defines AWPs and DPs as "whatever is listed in the pricing compendia." DJM 18. Alternatively, they contend that the terms are too uncertain to have any meaning. *Id.* Defendants are wrong on both counts.

First, the reference in the regulations to the pricing compendia is not intended or reasonably construed to be anything other than the source that DHS will use to locate reported drug prices. Rather, AWP and DP are defined by reference to the Estimated Acquisition Cost (EAC) of a drug product. Second, Defendants' new-found interpretation of AWP and DP is irrelevant to the issue of falsity because the Court's interpretation of those terms will govern. Furthermore, from the false claims perspective, even ambiguity of government terms does not foreclose defendants' liability for false claims.

a. AWP and DP Are Grounded In The Estimated Acquisition Cost of A Drug Product.

Defendants argue first that California has indeed defined the terms AWP and DP and they mean simply the prices listed in the pricing compendia, specifically FDB. DJM 18. Regardless what price the manufacturer reports or causes FDB to publish, or presumably whatever price FDB decides on a whim to publish, Defendants insist that such a price constitutes the AWP or

DP and it can never be false.[8] DJM 18, 19. The applicable regulations demonstrate that Defendants' position is frivolous.[9]

In Title 22 of the California Code of Regulations, section 51513 provides that drugs shall be reimbursed by Medi-Cal at the lower of Estimated Acquisition Cost, Federal Allowable Cost or Maximum Allowable Ingredient Cost. EAC for drug product was defined as "the Department's best estimate of the price generally and currently paid by providers," which was set as the "Average Wholesale Price minus 5 percent (AWP-5%)" or the Direct Price. § 51513(a)(6) (A), (B)[10]. The regulations then direct that AWP and DP were to be ascertained from the Department's primary price reference source, i.e. a compendium such as FDB. Accordingly, as well understood by Defendants (FAC ¶¶ 1, 36, 49),[11] the AWP or DP that they reported to FDB for use by State Medicaid programs and other third-party payors would be used by the State – in accordance with its regulation – as a benchmark to estimate acquisition cost, or

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8. Responding to a similar argument that Congress intended to allow manufacturers to control reimbursement, Judge Stearns noted: "The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual." *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 163 (D. Mass. 2003). And, as this Court has noted, the Department of Health and Human Services' Office of the Inspector General stated in 2003: "[I]t is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product." *In re Pharm. Indus. Average Wholesale Pricing Litig.*, 263 F. Supp. 2d 172, 180 n. 6 (D. Mass. 2003), quoting HHS, Office of the Inspector General, document titled "Compliance Program Guidance for Pharmaceutical Manufacturers" (dated April 2003) at 27.

9. There is also no factual record from which this Court could ascertain whether Defendants' actions in reporting inflated AWPs or DPs were ever premised on these supposed definitions of AWP and DP. Notably, Defendants submitted AWPs on a nationwide basis, and not simply for the isolated use of Medi-Cal.

10. This was the general reimbursement scheme in effect during most of the relevant period. Starting in 2002, the reimbursement formula was amended to include reference to average sale price as reported to the Department by a drug manufacturer, CAL. WELF. & INST. CODE § 14105.45(b), and the discount off AWP was increased to 10% in 2002 and 17% in 2004.

11. *See Heckler*, 467 U.S. at 64; *North Mem'l Med. Ctr.*, 59 F.3d at 739;*United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) ("Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment"); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 339 (D. Conn. 2004) (same).

"prices generally and currently paid by providers." § 51513(a)(6). Because these regulations must be interpreted in accordance with the purpose of the Medi-Cal program, AWPs and DPs must provide a reasonable basis for estimating acquisition cost. *See United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992) (regulations are interpreted so as to further program's purpose); *see also Pioneer Inv. Serv. Co. v. Brunswick Assocs. Ltd. Partnership*, 507 U.S. 380, 388 (1993) (in construing congressional enactment, court looks at "evident purpose" underlying it). Prices reported by Defendants that they know will be utilized by Medi-Cal, therefore, are false and violate the statute and regulations if the prices are reported without regard to estimated acquisition costs of providers.

Defendants rest their entire argument on a circular and misleading reading of a limited portion of the regulations. Cal. Code Regs., tit. 22, §§ 51513 and 51513.5 define AWP and DP in terms of where DHS is directed to obtain those reported prices. The regulations do not in any manner define the manner in which drug manufacturers are supposed to calculate or report their prices. The obvious fallacy of Defendants' argument is perhaps best illustrated by an analogy: a property tax regulation directs that taxes are to be assessed based on the price that a homeowner reports has been paid for a property. No one could argue that homeowners who lied about the price they paid would be able to defend that lie by claiming that price is defined as the price that they report, and therefore whatever they reported cannot be false.

The First Circuit has rejected the notion that a strict, literal reading of a provision in a government procurement policy could be applied when that reading would lead to an absurd result. In *United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992), the government accused a contractor of violating a provision that called for the reporting of all computer board

price discounts given to any non-governmental customer, at any time, in any manner. *Id.* at 1258. Although the First Circuit found that the procurement provision, read literally, was unintelligible, the provision was nonetheless deemed enforceable if defined pursuant to a practical interpretation. *Id.* at 1259-1260. In the instant case, it is the Defendants' interpretation of the statute and regulations that is unreasonable, and this Court should ascertain whether there is a reasonable, practical interpretation that should govern.

b. Defendants Cannot Be Permitted to Interpret the Regulations In Such a Way That They Can Report Whatever Prices They Want.

Presumably recognizing the absurdity of their position regarding the so-called California definitions of AWP and DP, Defendants proceed to argue that a failure to apply those definitions renders the terms "too uncertain to allow prosecution under the CFCA." DJM 20. This argument, too, must fail because it is clear that it is the Court's province to assign a meaning to statutes or regulations, and then to decide whether certain conduct is consistent with that meaning. *See, e.g.*, *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457 (9th Cir. 1999), (rejecting the argument that a defendant in a FCA case may always defeat the falsity requirement by demonstrating a reasonable interpretation of an ambiguous accounting standard); *United States v. Estate of Rogers*, 2001 WL 818160 (E.D. Tenn. 2001) ("[i]t is the defendant's compliance or lack of compliance with the nondiscretionary regulations, as interpreted by the courts, that determines whether the defendant's conduct results in the submission of false claims under the FCA. While the reasonableness of a defendant's interpretation of nondiscretionary regulations may be relevant to the separate issue of scienter and whether that defendant knowingly submitted a false claim, the issue of falsity is determined by whether the defendant's statements to the government were true and accurate in light of the applicable law").

The most that Defendants can argue in support of applying their own interpretation to a statutory or regulatory provision is that a *reasonable* interpretation of a statutory or regulatory term may preclude falsity. *E.g., United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998) (reasonable interpretation of ambiguous term may negate falsity); *United States ex rel. Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1048 (N.D. Ill. 1998) ("ambiguous statutory requirements, where no regulations further define those requirements, cannot hold a defendant to the government's strict interpretation, *so long as defendant's interpretation was reasonable*") (emphasis added). In *Cox*, where the issue turned on an air ambulance service submitting its claims in statute miles rather than nautical miles, the court found that plaintiff had alleged nothing to show that statute miles (which are the conventional 5,280 feet) were not an appropriate -- hence, not false – measure. *Id.* at 1026. Defendants' brief is void of any attempt to ascribe a reasonable meaning to the terms and then to demonstrate that their conduct met their own proffered interpretation. *See generally, Visiting Nurse Ass'n v. Thompson*, 378 F. Supp. 2d 75, 95 (E.D.N.Y. 2004) (rejecting defendants' attempt "to hide behind the general 'abundance of confusion and misdirection' that they contend surrounded … § 3205 to argue, in effect, that the dispute over the meaning and validity of § 3205 created blanket immunity").

In determining what is reasonable, it is well-established that undefined statutory or regulatory terms are to be given their plain meaning. *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (statutory construction begins with language used and assumption that ordinary meaning expresses legislative purpose); *Telematics Int'l, Inc. v. NEMLC Leasing Corp.*, 967 F.2d 703, 706 (1st Cir. 1992) (statutory language must be accorded

its ordinary meaning). An interpretation of the regulations at issue also cannot lead to the absurd result Defendants advocate. Instead, statutes and regulations should be construed in a commonsense manner, honoring plain meaning, and avoiding absurd or counter-intuitive results. *New York State Dairy Foods, Inc. v. Northeast Dairy Compact Comm.*, 198 F.3d 1, 9-10 (1st Cir. 1999); *Department of Alcoholic Beverage Control v. Alcoholic Beverage Control Appeals Bd.*, 128 Cal. App. 4th 1195, 1209 (2005) (a state department's regulations may not be interpreted in a manner that results in absurd consequences or defeats the core purposes of their adoption). Stripped of Defendants' arguments, therefore, the Court need only ascertain if the FAC adequately alleges that Defendants made false statements when they reported prices that are alleged to have no relationship to average wholesale prices or anyone's acquisition costs. Clearly, it does so. *See, e.g.*, FAC ¶¶ 44, 45, 54, 57, 60, 82, 91, 148.

c. AWP and DP Are Sufficiently Certain and Enforceable

Even assuming some ambiguity in the regulations, courts have held that ambiguity does not foreclose a finding of falsity under the FCA. In *United States ex rel. Walker v. R & F Properties.*, 433 F.3d 1349 (11th Cir. 2005), the court explained that the ambiguity of the term "incident to the services of a physician" did not preclude liability for false claims. The court stated,

> The district court erred by holding that any ambiguity … necessarily forecloses, as a matter of law, the falsity of claims submitted … . We agree that the regulatory language … was ambiguous. But we disagree as to the legal significance of that ambiguity. In opposition to LFM's motion for summary judgment, Walker submitted provisions from the [various interpretive sources] . . . At least some of these sources would support a finding that, in the Medicare community, the language was understood to mean that a physician had to be physically present in the office suite and otherwise more involved in a patient's course

of care.

Id. at 1356-57. *See also, United States v. White*, 765 F.2d 1469, 1481 (11th Cir. 1985) ("There is a line between estimates which reflect reasonably incurred expenses and estimates which are so grossly inflated when compared to actual costs that they are by their very nature fraudulent."); *Alliance of Auto Mfrs. v. Gwadosky*, 430 F.3d 30, 37 (1st Cir. 2005) (court cautions against "los[ing] sight of the forest while searching for trees" and holds that meaning and purpose of statute must be discerned from statute as a whole). Here, it is a short road from the use of AWP in the regulations to EAC and "prices generally and currently available to providers," both of which provide a clear grounding to the term AWP.

Defendants' cited cases are not to the contrary. In *People v. Duz-Mor Diagnostic Laboratory, Inc.*, 68 Cal. App. 4th 654 (1998), for example, the court's holding did not rest upon a finding that the CFCA manual and regulations were too complex. Instead, that court upheld the trial court's *factual finding* that Duz-Mor had "adopted the billing practice at issue here on the instructions of a Medi-Cal representative, and did not knowingly make a false claim." *Id.* at 672-673.

Cox, 29 F. Supp. 2d 1022, 1026, holds no differently, focusing on whether anything in the applicable regulations required defendants to submit claims in nautical miles rather than standard usage statute miles. In *United States ex rel. Gathings v. Bruno's, Inc.*, 54 F. Supp. 2d 1252 (M.D. Ala. 1999), the court did not find the challenged agreement to be ambiguous. To the contrary, the court explored the meaning of the contractual provision and found that defendants' conduct was in accordance with the provision. *Id.* at 1260.[12] Finally, in *United States ex rel.*

12. This Court's opinion in *United States ex rel. O'Keefe v. Sverdup Corp.*, 131 F. Supp. 2d 87 (D. Mass. 2001) does not address the significance of ambiguous terms in the context of false claims act claims, but merely holds as to one particular claim that the relator had not alleged that anything about the challenged statement was

Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1047 (ND. Ill. 1998), the district court did not find that regulations were ambiguous but, rather, found that it was "presented with a legitimate scientific dispute, not a fraud case." *Id.*

Particularly at this stage of the proceedings, Plaintiffs have adequately alleged that the reported AWPs and DPs were false. Any further issues regarding the meaning of AWP and DP cannot be resolved in the context of this motion to dismiss. *United States ex rel. Walker v. R & F Properties.*, 433 F.3d 1349 (11th Cir. 2005); *Harvard Coll.*, 323 F. Supp. 2d 151, 173. Defendants have come nowhere close to their burden of demonstrating that there is no set of facts under which Plaintiffs could prevail on their claims.

4. Defendants Are Subject to Liability under Cal. Government Code § 12651(a)(8) Because They Benefitted from Their False Reporting of Wholesale Drug Prices and Knew That Their Customers Were Submitting False Claims to the Government.

Defendants contend that Count III (CAL. GOV'T CODE § 12651(a)(8)) must be dismissed because Plaintiffs cannot plead that Defendants are "beneficiaries" and that they subsequently discovered the falsity of the claims at issue. DJM 26-27 Tellingly, Defendants cite to no authority to support this specious argument.

California Government Code section 12651(a)(8) imposes liability on anyone who "[i]s a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim." *Nowhere* in the CFCA does it state that the "beneficiary" must be the "actual recipient of government funds," as Defendants contend. DJM 26. This unduly restrictive reading of Section 12651(a)(8)

false. *Id.* Obviously, that is not the issue herein, where relator and California have alleged that the submitted AWPs and DPs for specified products were false.

impermissibly limits the plain language of the statute—which is prohibited by the principles of statutory construction. *See People v. Briceno*, 34 Cal. 4th 451, 459 (2004) ("'we turn first to the language of the statute, giving the words their ordinary meaning.' The statutory language must also be construed in the context of the statute as a whole and the overall statutory scheme . . . .") Consequently, California courts have declined to give such a restrictive interpretation to the false claims statute. *See Pomona*, 89 Cal. App. 4th at 802 (noting that CFCA liability does not depend upon a defendant's status as a direct recipient of a false claim).

The ordinary meaning of "beneficiary" is defined in the dictionary as "[t]he recipient of funds or other benefits." *See* Websters Online Dictionary, http://www.websters-online-dictionary.org/definition/beneficiary. Here, as alleged, Defendants benefit in part from their false reporting of wholesale prices by, among other things, obtaining a competitive edge and greater market share over competitors who offer wholesalers the same drug. By obtaining a greater market share, Defendants make more profits and thereby indirectly receive the government funds that are being used to fuel those profits.[13] In addition, Defendants' contention that Plaintiffs have failed to adequately allege that Defendants discovered the falsity of the claims at issue is

[13]California's statutory scheme also supports this interpretation. Several other subdivisions of Section 12651 clearly apply to situations where the defendant is not actually receiving the government's funds, but somehow aids in the submission of a false claim. *See* CAL. GOV'T CODE § 12651(a)(2) ("Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision."), (a)(3) ("Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision."), (a)(7) ("Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.")

Similarly, federal courts have long held that liability under the federal FCA does not depend upon the defendant's status as a recipient or beneficiary of the false claim; all that is required is submission of a false claim. *Harrison v. Westinghouse Savannah River Co.* 176 F.3d 776, 792 (4th Cir.1999); *United States v. Rivera*, 55 F.3d at 709-710 ("in deciding whether a given false statement is a claim or demand for payment, a court should look to see if, within the payment scheme, the statement has the practical purpose and effect, and poses the attendant risk, of inducing wrongful payment."); *United States ex rel. Schwedt v. Planning Research Corp.*, 313 U.S. App. D.C. 200 (D.C. Cir. 1995) ("A submission need not be an actual invoice to be a 'claim' or 'statement' under the Act."); *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) ("this remedial statute reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.").

belied by the allegations of the FAC. The FAC alleges that "[t]he Medi-Cal reimbursement system for the Defendants' drugs was based upon the reported prices and each Defendant knew this, yet caused the reporting of the false and misleading prices that they knew would be used by Medi-Cal to determine reimbursement amounts." FAC ¶ 49; *see also* FAC ¶¶ 50-176 (allegations specific to each defendant). It was not necessary for Defendants to "discover" the falsity of the claims at issue, because Defendants were already well aware of the falsely inflated prices - i.e., the AWPs and DPs - which *they* had derived and submitted to the same compendia employed by Medi-Cal to adjudicate the very claims they knew would be submitted for reimbursement on their products. "[T]he claim itself need not be false but only need be underpinned by fraud." *Pomona*, 89 Cal. App. 4th at 802. Defendants *were instrumental in creating the false claims* and knew that their conduct would result in false claims being submitted to the government.

5. California's FAC Sufficiently Alleges Violations of the Medi-Cal Anti-Kickback Statute Giving Rise to CFCA Liability.

The basis for Counts IV and V of the FAC (FAC ¶¶ 190-201) is the allegation that Defendants engaged in acts which violate the state's anti-kickback statute ("AKS"), California Welfare and Institutions Code section 14107.2[14]. Defendants violated the AKS, as Plaintiffs allege, by offering or paying, or causing to be offered and paid, either directly or indirectly and

14. § 14107.2. Kickbacks, bribes or rebates; punishment
(a) Any person who solicits or receives any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration . . .
. . .
(b) Any person who offers or pays any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration . . .
. . .
(d) For purposes of this section "kickback" means a rebate or anything of value or advantage, present or prospective, or any promise or undertaking to give any such rebate or thing of value or advantage, with a corrupt intent to unlawfully influence the person to whom it is given in actions undertaken by that person in his or her public, professional, or official capacity.

overtly or covertly, remuneration in cash or other consideration to the huge number of Medi-Cal providers who purchased Defendants' drugs. FAC ¶¶ 191-194, 197-20[15]. In violating the anti-kickback statute, Defendants thereby induced Medi-Cal providers to purchase Defendants' drugs named in the FAC - - and other drugs - - knowing that Medi-Cal would remunerate the providers for Defendants' drugs, and would do so through paid claims which were based upon prices grossly in excess of the generally and currently available prices for those drugs - - i.e., false claims. Count IV, FAC ¶¶ 191-195. In violating the anti-kickback statute, Defendants also induced Medi-Cal providers to file false statements or records in support of the providers' claims for reimbursement. Count V, FAC ¶¶ 196-201.

Defendants argue that their alleged misconduct does not constitute a violation of the anti-kickback statute. DJM 28-29. They also erroneously assert that "remuneration" under the AKS is "*defined*" therein as "any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind." DJM 29 (emphasis added). The statute quoted in footnote 14, above, actually provides that "remuneration" "*includ*[*es*], *but* [*is*] *not restricted to, any kickback, bribe, . . .* " CAL. WELF. & INST. CODE § 14107.2(a)(emphasis added).

Defendants also argue, incorrectly, that the underlying commercial transactions did not constitute offers or payments of remuneration because, according to the Defendants, they are only alleged to have reported inflated prices to the pricing compendia and thus did not "offer" remuneration. DJM 28-29. Like its federal counterpart, the AKS addresses the instant factual scenario when it proscribes the offering or payment of "any remuneration, including but not

15. As specifically alleged throughout the FAC, Defendants arranged for their Medi-Cal provider customers to receive remuneration, in the form of inflated reimbursement, as an inducement for the customers to purchase their drugs. FAC ¶¶ 44, 45, 54, 58, 63, 67, 78, 88, 92, 103, 117, 121, 127, 139, 150, 175, 191-194, 197-200.

restricted to, any kickback, bribe, or rebate, directly *or indirectly*, overtly *or covertly*, in cash *or in valuable consideration of any kind*.....(2) In return for the purchasing....or ordering of any goods.....or merchandise for which payment may be made, in whole or in part under this Chapter 8..." CAL. WELF. & INST. CODE § 14107.2(b)(emphasis added). The statute does not, as the Defendants contend, require a direct payment by the manufacturer to the Medi-Cal provider.[16] Instead, it recognizes that the realities of commercial arrangements (particularly those designed to defraud the government) are such that the actionable conduct targeted by the statute includes any consideration indirectly transferred from one actor to another, not necessarily paid or offered "directly," and which may not take the prototypic form of a manufacturer visiting the pharmacy or the doctor and handing them cash to purchase the manufacturer's drugs. The statute explicitly contemplates remuneration that is paid or offered or otherwise transmitted "indirectly". Moreover, the remuneration need not even be in cash, but can be "valuable consideration of any kind." CAL. WELF. & INST. CODE § 14107.2(b).

The remuneration here was the inflated spread that the Defendant manufacturers created when they reported their prices to the compendia, knowing they would be used by Medi-Cal to set reimbursement amounts. The fact that the Medi-Cal provider must submit a claim before it is paid (and in order to receive) the remuneration merely means that the remuneration was paid indirectly, while tied directly to the sale of drugs paid for by Medi-Cal. The remuneration was thus offered *and* paid. It was offered when the manufacturer marketed and sold the drug after reporting the inflated prices, because the inflated "spread" on the drug was an existing factor in the sales transaction. The payoff for the Medi-Cal provider customer came when Medi-Cal paid

16. The FAC also alleges that the Defendants made the exact kinds of direct rebates and payments that the Defendants erroneously contend are required by the Medi-Cal AKS. FAC ¶ 45. Accordingly, their motion to dismiss these Counts should be denied even under the Defendants' flawed construction of the statute.

the claims that the Defendant manufacturer knew would be submitted.[17]

Defendants also misapprehend the core principle that an AKS violation can independently form the basis of a CFCA claim. DJM 27-29. The pertinent provisions of the CFCA and the AKS are the same as their federal counterparts (31 U.S.C. § 3729 (a) and 42 U.S.C. § 1320a-7b). The federal courts addressing this issue have held that liability under the federal False Claims Act will arise where the federal anti-kickback statute has been violated in connection with the submission of claims for products or services paid for by the Medicare or Medicaid programs. In *McNutt v. Haleville Med. Supplies Inc.*, 423 F.3d 1256 (11th Cir. 2005), the government alleged violations of 42 U.S.C. § 1320a-7b(b)(the federal AKS). On that basis, the government alleged that defendants had "knowingly presented, or knowingly caused to be presented, false or fraudulent claims for payment in violation of the False Claims Act," since a violation of the federal AKS rendered defendants ineligible to participate in the Medicare program. *Id*. at 1258-59. The court tersely explained its affirmance of the district court's denial of defendants' motion to dismiss:

> The government has alleged a valid claim against [Defendants]. The government has alleged that the [Defendants] violated the Anti-Kickback Statute; compliance with the Statute is necessary

17. Defendants rely on the Ninth Circuit's decision in *United States v. Duz-Mor Diagnostic Lab.*, 650 F. 2d 223 (9th Cir. 1981), in asserting that the FAC fails to allege an "offer". *Duz-Mor* provides no support for Defendants' position. First, *Duz-Mor* did not even involve the actual payment of remuneration, as alleged in the FAC, because the FBI interrupted the transaction before it was actually consummated. The kickback violations alleged in the present case are based on both offers *and payments*. Second, the Court in *Duz-Mor* was not presented with an indirect remuneration scheme and the FAC alleges both direct payments, such as the rebates present in *Duz-Mor*, and indirect payments in the form of inflated reimbursement caused by the inflated spreads created for the purpose of inducing purposes. Third, the FAC alleges actual consummated sales transactions, i.e., that the Defendants each offered and sold their specified drugs after creating the specified spreads as an inducement. Fourth, *Duz-Mor* is a 1981 case that predates the important 1986 amendments to the Federal Anti-Kickback Statute found in the Medicare Medicaid Program Protection Act of 1987, and which were later applied and explained by the Ninth Circuit in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), which emphasized that Congress explicitly expanded the protections of the statute beyond actual bribes, kick-backs and rebates to, like the Medi-Cal AKS, encompass "any remuneration." *Id.* at 1398; 42 U.S.C. § 1320a-7b.

> for reimbursement under the Medicare program; and the [Defendants] submitted claims for reimbursement knowing that they were ineligible for the payments demanded in those claims. This allegation is not general or speculative: the government has identified as false numerous specific claims the [Defendants] made to the federal government.

Id. at 1260. See also *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615-16 (N.D. Ill. 2003) ("The [federal] anti-kickback statute criminalizes receiving remuneration intended to affect decisions to purchase supplies for which payment may be made under Medicare . . . Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place.")[18] There is no substance to Defendants' unsupported argument that violations of the AKS cannot form the basis for Plaintiffs' CFCA allegations in Counts IV and V of the FAC.

6. The AKS Is Not Pre-empted By The Federal Anti-Kickback Statute, And Congress Has Encouraged State Statutes Protecting Medicaid.

Defendants ask this Court to dismiss the Medi-Cal AKS Counts (IV and V), yet articulate no reasoning that would overcome the strong presumption against federal pre-emption, *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), that is applicable to claims of either express or implied pre-emption. *Bronco Wine Co. v. Jolly*, 33 Cal.4th 943, 958, fn. 11 (2004). The

18. The Medi-Cal AKS and CFCA also exist to insure the integrity of the Medicaid Program, and the State of California must also presume that Medi-Cal claims are in compliance with applicable laws and thus eligible for reimbursement. The CFCA, like its federal counterpart, prohibits the presentment of false claims for payment or approval and the making or using of false records *or statements* to get false claims paid or approved, as well *as causing* false claims to be presented or false records or statements to be made or used to get the claims paid. CAL. GOV'T CODE § 12651(a) (1),(2). The claims at issue in this case are false because they were paid at amounts substantially inflated above any reasonable estimate of acquisition cost, and the inflated amounts were caused by the price reports the Defendants made or caused to be made in order to cause Medi-Cal to pay claims based on the inflated spreads. Accordingly, if the Defendants violated the AKS by using the spread to create a financial inducement, they also caused the claims in question to be paid based upon false statements about cost, and thus caused the presentment of false claims or the making or use of false records or statements to get false claims paid or approved.

presumption also applies in determining the scope of pre-emption, *Medtronic*, 518 U.S. at 485, and is especially strong where, as here, the joint federal and state healthcare program statutes are part of a "common purpose" pursued by the federal and state governments. *Pharm. Research & Mfrs. Of Am. v. Walsh*, 538 U.S. 644, 666 (2003), followed by this Court in *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187,198 (D. Mass. 2004). The U.S. Supreme Court recently reaffirmed this principle in *Bates v. Dow Agrosciences L.L.C.*, __ U.S. __, 125 S. Ct. 1788, 1801 (2005) ("we would nevertheless have a duty to accept the reading that disfavors pre-emption. . . . In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" (internal quotation and citations omitted).)

In this respect, it is important to consider that "the California Legislature, when it enacted Welfare and Institutions Code section 14107.2, was adopting the federal statutes." *People v. Palma*, 40 Cal. App. 4th 1559, 1566 (1995). In *People v. Duz-Mor Diagnostic Laboratory, Inc.*, 68 Cal. App. 4th 654, 669-670 (1998), the court held that the Medi-Cal AKS was not unconstitutional as phrased, even though it does not contain a "knowing and willful" requirement, and therefore does not require a specific intent element. *Id*. at 671. Significantly, the *Duz-Mor* court did not find any conflict between the California and federal anti-kickback statutes. *Id.*

More importantly, Defendants fail to satisfy their burden to show any "clear and manifest" intent by Congress to preempt the Medi-Cal AKS. There is no clause or language in 42 U.S.C. § 1320a-7b indicating an intent to preempt similar state statutes.[19] To the contrary,

19. To the contrary, Congress requires the States to enact legislation combating Medicaid fraud and, just last month, passed, and the President signed, a law providing incentives for the states to enact false claims acts to protect Medicaid, something California did twenty years ago. *See* Deficit Reduction Omnibus Reconciliation Act of

courts have held that the federal anti-kickback law does not pre-empt other statutory schemes that may be interpreted to conflict with it, including the Federal Claims Act, 31 U.S.C. §§ 3729-3731, and federal common law. *See United States v. General Dynamics Corp.*, 19 F.3d 770, 776-777 (2d Cir. 1994) (finding that other courts "have allowed the United States to seek recovery for kickbacks under the FCA or common law, without finding any preclusion of these remedies by the AKA.") Defendants issue only conclusory assertions that the Medi-Cal AKS does not contain the "knowing and willful" language of the federal statute and has a "narrower" safe-harbor provision than the federal statute (DJM 30), without citing any authority.

A careful review of the only two cases cited by the Defendants confirms that their pre-emption claim fails. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), in no way supports federal preemption of the Medi-Cal AKS, because that decision recognized: "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one." *Id.* at 75. The other case cited by the Defendants, *State v. Harden*, 873 So. 2d 352 (Fla. Dist. Ct. App. 3d Dist. 2004), misapplied the pre-emption standard and would not support pre-emption here even if it had significant precedential value.

Harden found that Florida's Medicaid anti-kick back statute (Fla. Stat. § 409.920(2)) was pre-empted because the Florida statue did not contain a "safe harbor" provision similar to the one contained in the federal statute, and the Florida statute's requirement of "knowing", but not expressly "wilful" conduct. A different panel of the same court revisited pre-emption in *State v. Wolland*, 902 So. 2d 278 (Fla. Dist. Ct. App. 3d Dist. 2005). *Wolland* stakes out a substantially

2005, signed by the President on February 8, 2006 as Public Law 109-171, SECTION 6023 "Encouraging the Enactment of State False Claims Acts."

modified position on the pre-emption issue (compared to *Harden*), and pointedly cites this Court's decision declining to find pre-emption in *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 198 (D. Mass. 2004), while ascribing weight to the strong presumption against pre-emption in the area of the joint federal-state Medicaid Program. *See Wolland*, 902 So.2d at 282. In particular, the *Wolland* court found that the absence of the word "wilfully" did not cause the Florida Medicaid fraud and anti-kickback statute to be pre-empted by federal law, and distinguished *Harden* in noting that it "clearly turned on the absence of safe-harbor provisions..." 902 So.2d at 286.[20]

The Medi-Cal AKS is consistent with the "common purpose" of the joint federal-state Medicaid Program and should not be deemed pre-empted by the federal law it is patterned after. Also, the "safe harbor" provision of the federal statute speaks to "disclosed" discounts, not the conduct implicated in Defendants' inflated price reports. Finally, the Medi-Cal AKS contains a "safe harbor" provision substantially the same as its federal counterpart.[21]

7. The FAC States A Claim For Medi-Cal Drugs Reimbursed Under A MAIC Or A FUL.

Defendants advance several arguments asserting that Plaintiffs' claims should be dismissed, generally, "with respect to drugs for which California did not pay reimbursement on the basis of AWP or DP, but rather pursuant to Medi-Cal's other formulas for reimbursement, including MAIC, FAC (also known as "FUL"), or the amount charged by provider." DJM 31.

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20. Later, the Florida Fifth District Court of Appeal followed *Harden* on the intent issue in *State of Florida v. Rubio*, 917 So. 2d 383 (Fla. Dist. Ct. App. 5th Dist. 2005), another criminal case involving the false statements provision of Florida's Medicaid Fraud Statute. *Rubio*, however, was based on a specific provision of the Florida statute (FLA. STAT. § 409.920(1)(d)) which defined "knowingly" to include the language "should be aware." *Id*. at 388.

21. Compare CAL. WELF. & INST. CODE § 14107.2(c)(2) with 42 U.S.C. § 1320a-7b(3)(A).

These arguments fail for the following reasons.

First, as to drugs reimbursed under a FUL, Defendants incorrectly imply that FULs are set through a mechanism divorced from any of the allegedly false pricing information they may provide. In Medi-Cal regulations, FULs are synonymous with the DHS term "Federal Allowable Cost" (FAC). The Centers for Medicare and Medicaid Services (CMS) determines FULs for certain multiple-source drugs (i.e., generics and brand name counterparts) whenever the compendia indicate there are at least three suppliers of the same therapeutically equivalent drugs. The FUL designation, and price, "is based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally." 42 C.F.R. § 447.332, subd. (a)(1)(ii). As the preceding quote indicates, the prices used in setting the FUL are prices reported by drug manufacturers to the compendia, i.e., their Wholesale Acquisition Cost (WAC), AWP, DP, or others. If no WACs were reported but a FUL was nonetheless set by CMS for a particular drug, that FUL would be based upon other prices reported to the compendia in the list used by CMS to set the FUL, such as AWP or DP.

Furthermore, as alleged in the FAC and documented in the Myers and Stauffer report (FAC Exh. L), there are significant spreads between the FUL prices and the prices that were generally and currently available to providers for the drugs that were reimbursed by Medi-Cal. For example, in April 2003, a 17 gram albuterol inhaler manufactured by Defendant Warrick Pharmaceuticals (NDC# 59930156001) was reimbursed by DHS at a FUL amount of $0.88 per gram. Yet in 2003, the wholesale cost of the inhaler as reflected in contract documents was approximately $0.13 per gram. Using a FUL, DHS was reimbursing at 676% of the true wholesale cost for Albuterol, while pharmacies and physicians in California routinely purchased

the drug for, at most, a small amount over the wholesale cost. FAC ¶ 48.This Court has previously instructed that:

> [i]n light of the allegations and concessions concerning an industry-wide practice of inflating AWP's, the Court rejects arguments that Plaintiffs must allege a specific spread for each drug, so long as sufficient facts were alleged to infer a fraudulent scheme by each particular Defendant manufacturer (i.e., government investigations concerning that company, internal company documents, specific alleged fraudulent spreads on other drugs manufactured by that company and the like).

In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196, 209 (D. Mass. 2004). Plaintiffs have adequately alleged such spreads in their exhibits, and the Myers and Stauffer report found that even for Medi-Cal reimbursed multi-source drugs with FUL prices, the weighted average acquisition cost enjoyed by provider pharmacies surveyed was 12.7% of the AWP and 38.7% of the FUL. FAC Exh. 12, at 4.

Defendants also attempt traction in quoting a portion of this Court's class certification decision in *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass 2005), in which the Court allowed class certification of third-party payors (TPPs) and consumers regarding physician-administered drugs, but limited the drugs encompassed in the certification to generics dispensed through a TPP-physician contract which are "expressly predicated on AWP." *Id*.; DJM 33. However, Defendants misconstrue the import of the quoted language, which appears within the Court's analysis of Federal Rule of Civil Procedure Rule 23(b)(3), in connection with class manageability. The Court noted the difficulties inherent in charting the inflated pricing claims for each of many different Maximum Allowable Costs (MACs), each set by a different payor pursuant to a discrete commercial contract. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 91.

Here, there is at any one time a single FUL formula set by the federal government, and a single MAIC methodology set by the State of California. Defendants misapprehend the concern underlying this Court's "expressly predicated on AWP" limitation. There are no class certification issues raised in the FAC, and this case does not encompass multiple commercial contracts with varying terms driving multiple different reimbursement formulae. Second, as to their MAIC argument, Defendants correctly note that Plaintiffs do not allege that MAIC appears in any reporting service. However, they incorrectly assert that MAIC is a term "[w]ithout any causal link to Defendants' conduct regarding AWP and Direct Price," so that "Plaintiffs' allegations relating to drugs reimbursed on MAIC must fail." DJM 32.[22]

Until September 30, 2002, California law provided that "[DHS] shall base a MAIC on a reference drug brand which is generically equivalent to the innovator brand, and which is manufactured by a company with production capability to meet the statewide needs of the Medi-Cal program for that drug." CAL. WELF. & INST. CODE § 14105.45 (b)(1) (2001). There was no further reimbursement formula for setting a MAIC, so that if a drug was designated as a MAIC, it was reimbursed based on AWP minus 5%, consistent with Title 22 of the California Code of Regulations, section 51513. The falsity of that AWP is satisfactorily alleged in the FAC.[23] Even

22. First, of the 174 drugs listed in the exhibits, very few were paid under a MAIC. Comparing the list of drugs on the MAIC and FAC List which is set forth in the DHS Providers Manual, only 16 of the 174 drugs listed in Plaintiffs' exhibits were designated as MAIC drugs in 2005. The National Pharmaceutical Council (NPC), an entity funded by drug manufacturers, explains in its Report entitled *Pharmaceutical Benefits Under State Medical Assistance Programs, 2004*, that "[California] imposes a combination of Federal and State-specific limits on generic drugs. Maximum Allowable Ingredient Costs (MAICs) are established for about 50 multi-source items." *Id*., *State Profiles A-F*, p. California-3. The exhibits to the FAC, i.e., the drugs on which Plaintiffs are suing, encompass only some of the drugs within the Medi-Cal formulary, whereas the statement in the NPC 2004 report quoted above appears to refer to the entire Medi-Cal formulary.

23. Effective September 30, 2002, CAL. WELF. & INST. CODE § 14105.46 was enacted (although repealed in September 2004), in conjunction with an amendment to the language of CAL. WELF. & INST. CODE § 14105.45. Under current section 14105.45 (effective August 2004), DHS is directed to set MAICs pursuant to a particular formulaic inquiry which sets MAICs as the mean of the wholesale selling prices it collects: "(A) The department

after 2002, when MAICs were not set on reported prices, the reimbursement formula always paid "the lower of" MAIC, AWP, or other prices. Had Defendants' AWPs not been falsely inflated, they would often have been lower than the MAICs and would have set the reimbursement price. If anything, this would raise a damages question, which is not appropriately at issue in a motion to dismiss analysis.

C. ALL COUNTS OF THE AMENDED COMPLAINT SATISFY THE PLEADING REQUIREMENTS OF RULE 9(b).

The plaintiff must allege the circumstances of the fraud, but is not required to plead all of the evidence or facts supporting it. *Parke-Davis*, 147 F. Supp. 2d at 47. *See* 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1298, at 625-26 (2nd ed. 1990) (stating that Rule 9(b) does not require plaintiff to resort to "fact pleading.") In addition, this Court has held,

> [W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the FCA have not placed the bar so high as to require pleading with total insight.

Parke-Davis, 147 F. Supp. 2d at 49. *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1049 (S.D. Tex. 1998) (holding relator satisfied Rule 9(b) by alleging the "basic framework, procedures, the nature of the fraudulent scheme, and the financial arrangements and inducements among the parties and physicians that give rise to

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shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.

> (B) The department shall notify each selected wholesale drug distributor, in writing, that the wholesale drug distributor has been identified as a source of wholesale selling price information."

CAL. WELF. & INST. CODE § 14105.45(b)(3)(A),(B).

Relator's belief that fraud has occurred.")

The FAC contains allegations of fraud sufficient to satisfy the pleading requirements under Rule 9(b) in the context of the FCA. Consistent with this Court's prior opinions regarding Rule 9(b), Plaintiffs have alleged a detailed fraudulent scheme and have stated the specific drugs sold by each Defendant and their alleged fraudulent AWP figures. *In Re Pharm. Indus. Average Wholesale Pricing Litig.*, 321 F. Supp. 2d 187, 207 (D. Mass. 2004). The FAC provides specific industry insider price information available to Ven-A-Care, specific price information obtained in the Attorney General's investigation, and the false prices that the specific Defendants knowingly caused to be reported. FAC ¶¶ 50-176. In addition, for each drug product at issue, the Defendant-specific exhibits identify the: (1) drug name; (2) corresponding National Drug Code (NDC); (3) date; (4) AWP; (5) Cost of Drug Product (CDP); (6) market price per unit; and, (7) source of that market price.

Moreover, the FAC adequately discloses the "who, what, when, where, and how" of the fraudulent scheme. *Parke-Davis*, 147 F. Supp. 2d at 47. Each of the named Defendants is "who" made the false pricing representations. FAC ¶¶ 4-22. The fraudulent DPs or AWPs published in pricing compendia are "what" is alleged. FAC ¶ 44. The fraudulent scheme occurred "when" false pricing representations were made on or before January 1994 through the present. FAC ¶ 43. The pricing information submitted to FDB is "where" the conduct occurred. FAC ¶ 43. Finally, each of the Defendants knowingly made false representations to FDB with knowledge that Medi-Cal used these reported prices for setting and paying reimbursement amounts on claims for the Defendants' drugs, and which would cause the claims for such reimbursements to be false. FAC ¶ 49. This explains "how" the fraudulent scheme occurred.

Plaintiffs have satisfied the *Karvelas* test by providing information that identifies both the false statements in support of claims and the false claims for payment that were submitted to the government. *Karvelas*, 360 F.3d at 232-233.[24] The FAC exhibits contain details concerning: (1) each CDP at issue, which indicates the amount of money charged to the government; and, (2) each NDC at issue, which represents the particular goods for which the government was billed. As recognized by the Defendants, *Karvelas* does not set forth a checklist of mandatory pleading requirements. *Id.* at 233. Rather, *Karvelas* establishes that some characteristics regarding some of the claims must be pleaded in order to satisfy Rule 9(b). *Id.* Accordingly, Plaintiffs have complied with *Karvelas* by providing details concerning the amount of money charged to the government and the particular goods for which the government was billed.

Although Plaintiffs' FAC here meets the *Karvelas* requirement for details, this case differs from *Karvelas*.[25] While *Karvelas* involved alleged false claims submitted by a single hospital over a three-year period, the case at bar concerns the submission and reimbursement of millions of fraudulent claims over more than a decade. The individuals involved in the billing include thousands of providers participating in the Medi-Cal pharmacy program, who purchased

24. There were well over 700,000,000 total claims for Medi-Cal reimbursement filed by providers during the period at issue in the FAC. FAC ¶ 39. Defendants' drugs were the subject of many millions of such claims. Plaintiffs are prepared, if necessary to adjudicate Defendants' motion to dismiss, to provide the Court with electronic or paper versions of the millions of pharmacy and physician claims, but this procedure will involve the submission of a voluminous mass of documents.

25. The present case is also distinguishable from both *United States ex rel. Clausen* v. *Lab. Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002) and *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005). In *Clausen*, a "corporate outsider" made speculative assertions that false claims "must have been submitted, were likely submitted, or should have been submitted to the Government." *Clausen*, 290 F.3d at 1311. In the case at bar, Plaintiffs have firsthand knowledge of Defendants' pricing practices and the FAC adequately alleges that providers submit claims to Medi-Cal that are reimbursed based on Defendants' reported prices. In *Corsello*, the relator's complaint was deficient under Rule 9(b) because it "did not explain why he believe[d] fraudulent claims were ultimately submitted." *Corsello*, 428 F.3d at 1014. In the present case, Plaintiffs have sufficiently alleged that inflated claims were submitted to Medi-Cal for reimbursement based on false and excessive pricing information Defendants reported to FDB. FAC ¶ 43. Accordingly, Plaintiffs' allegations concerning the Defendants' fraudulent scheme provide a factual basis to conclude that false claims were actually submitted to the government.

the drugs manufactured by Defendants. Producing the date of each claim, its identification number, and the content of each claim form submitted would result in voluminous documents which would be irrelevant. During the ten-year period alleged in the FAC, Medi-Cal paid a total of 672,665,335 pharmacy claims, including claims for drugs manufactured by Defendants. FAC ¶ 39. Even if the claims at issue associated with the Defendants constituted only 1% of the paid claims during this time period (and the percentage is much higher), Defendants would argue, apparently, that the claims detail for each of the 6.7 million claims must be alleged by Plaintiffs. Indeed, requiring Plaintiffs to refer to the specific instances underlying each of the millions of fraudulent claims at issue "would undermine Rule 8's admonishment to keep pleadings simplistic." *United States ex rel. Pogue v. American Healthcorp*, 977 F. Supp. 1329, 1333 (M.D. Tenn. 1997). In light of the lengthy period and the large number of false claims involved in the FAC, requiring Plaintiffs to allege the particulars of each claim submitted to the government would result in an unmanageable pleading and would upset the balance between Rule 8(a) and Rule 9(b). *Id.*

1. Counts II and V of the Amended Complaint Satisfy the Pleading Requirements of Rule 9(b)

Counts II and V clearly satisfy the Rule 9(b) requirements by sufficiently describing the "false records or statement[s]" that Defendants caused to be made in violation of California Government Code section 12651(a)(2); namely, the falsely inflated prices reported by the compendia. Although Defendants attempt to distinguish between pricing information submitted to the compendia and the prices published by the compendia, Plaintiffs have clearly alleged that the manufacturers control the prices that are reported to the compendia. FAC ¶ 34. As alleged with particularity, FDB asserts that all pricing information is supplied and verified by the

manufacturers and that there is no independent review of those prices for accuracy. FAC ¶ 34. Consequently, the pricing information submitted by Defendants to the compendia and the pricing information published by FDB *derive identically from Defendants*. The FAC also specifically alleges that the Defendants caused the inflated Medi-Cal reimbursements by reporting false and excessive prices for their products to FDB. FAC ¶ 43. As previously explained, the "who, what, when, where, and how" of the fraudulent representations that Defendants caused to be made have been sufficiently disclosed.

2. Counts IV and V of the Amended Complaint Satisfy the Pleading Requirements of Rule 9(b).

Counts IV and V adequately allege that the Defendants knew that the prices charged to their customers for the identified pharmaceuticals were significantly less than the prices and costs represented by the Defendants and upon which the Defendants knew Medi-Cal claims would be approved and paid. FAC ¶¶ 191, 197. Accordingly, Defendants used the "spread" - - the difference between the market price of a drug and its CDP - - as an unlawful financial inducement to increase their market share and profit in violation of California Welfare and Institutions Code section14107.2.[26] That is, Defendants caused illegal remuneration to be paid to their customers in the form of inflated Medi-Cal reimbursements.

As this Court recognized in *Parke-Davis*, 147 F. Supp. 2d at 47, "where facts underlying the fraud are peculiarly within the defendants' control', a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision," (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)). Nonetheless, as the exhibits to the FAC

26. For instance, various memoranda issued by Dey personnel reveal the company's objective to use the spread to compete with competitors' drugs and gain market share. Dey marketed its drugs by emphasizing to customers the "spread" profit they would make by purchasing Dey's products at a price well below Medi-Cal reimbursement levels that were based on the inflated AWP. FAC ¶ 83.

amply demonstrate, Plaintiffs have alleged facts demonstrating the spread for each drug at issue for the entire period of time pertinent to that drug. In sum, Counts I through V of the FAC satisfy the pleading requirements under Rule 9(b) and should not be dismissed.

III.
CONCLUSION

For all the foregoing reasons, Plaintiffs respectfully request that Defendants' Motion to Dismiss the First Amended Complaint in Intervention be denied in its entirety.

Respectfully submitted,
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Attorney General for the State of California

Dated: March 2, 2006

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REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), Plaintiffs hereby request a hearing for oral argument on this Motion to Dismiss.

Dated: March 2, 2006

/s/ Nicholas N. Paul
NICHOLAS N. PAUL
Supervising Deputy Attorney General

CERTIFICATE OF SERVICE

I, Nicholas N. Paul, hereby certify that on March 2, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS THE FIRST AMENDED COMPLAINT IN INTERVENTION** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: March 2, 2006

/s/ Nicholas N. Paul
NICHOLAS N. PAUL
Supervising Deputy Attorney General